Illinois Department of PUBLIC HEALTH

Pat Quinn, Governor
LaMar Hasbrouck, MD, MPH, Director

525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.idph.state.il.us

MEMORANDUM

TO: Clinical Laboratories, Healthcare Providers, Hospitals, Healthcare Facilities, and Local Health Departments (LHDs)

FROM**:** IDPH Division of Laboratories and Division of Infectious Diseases

DATE: August 20, 2014

SUBJECT: HEALTH ALERT: INTERIM IDPH LABORATORY GUIDELINES FOR SUBMITTING SPECIMENS FROM CASES OR SUSPECTED CASES OF EBOLA VIRUS DISEASE (EVD)

The purpose of this document is to provide guidance to medical providers, laboratories and public health practitioners on the evaluation and case management for suspect and confirmed cases of Ebola Virus Disease.

The following guidelines are based on materials developed by the New York State and New York City clinical and public health laboratories and is directed to facilities that may receive and test specimens from patients suspected or confirmed as having Ebola virus Disease (EVD).

Please distribute <u>immediately</u> to the Clinical Lab Director, Infection Control Department, Hospital Administrator, Emergency Department, Infectious Disease Department, Pediatrics, Medical Director, Director of Nursing, Laboratory Service, and all Patient Care Areas

IMPORTANT POINTS FOR SUBMITTING SPECIMENS TO BE TESTED FOR EBV

1. **Prior authorization for testing must be obtained from the IDPH Division of Infectious Disease before specimens are submitted. Specimens received without authorization will not be tested.**

2. Unless otherwise specified, all testing for Ebola virus must be submitted to the IDPH Division of Laboratories for routing to the Centers for Disease Control (CDC) and Prevention.

3. Specimens should only be submitted from persons under investigation (PUI) who are either **high** or **low** risk for exposure to Ebola virus for whom an alternative diagnosis has not yet been determined. Please refer to following CDC website for definitions of probable and confirmed cases, and those for high risk and low risk exposures: http://www.cdc.gov/vhf/ebola/hcp/case-definition.html

4. Specimens will be tested for the presence of Ebola Virus RNA using a real-time reverse transcriptase polymerase chain reaction (rt-RT-PCR) recently FDA-cleared under Emergency Use Authorization (EUA). Serological testing is also available.

   NOTE: A negative rt-RT-PCR assay for the detection of Ebola virus RNA is only definitive if the specimen was collected at least 3 days after the onset of symptoms.

5. **The only specimen that is FDA-cleared for testing is EDTA-whole blood**. Submit whole blood or separated plasma (preferred). Heparin-treated blood is NOT acceptable and will be rejected. Plastic specimen tubes are required.

6. **Prior to shipping specimens, please contact the nearest IDPH laboratory and ask to speak about Ebola testing. Specimens must be shipped to the IDPH laboratory on ice packs. Include the standard IDPH requisition and CDC-PUI investigation forms.**

   Chicago: 312-793-4760
   Springfield: 217-782-6562
   Carbondale: 618-457-6995

IMPORTANT POINTS FOR THE COLLECTION AND HANDLING OF SPECIMENS

1. Ebola virus is transmitted through direct contact with blood or body fluids, or contact with environments contaminated with blood or body fluids. There is no evidence of airborne transmission.

2. Ebola virus is readily inactivated by standard heat and chemical inactivation procedures used in microbiology laboratories.

3. Procedures for the collection, handling, and testing of specimens for EVD have been issued by the CDC and are posted at the following site: http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

4. Laboratory testing should be limited to testing essential for patient care. (See transcript of the COCA calls "What U.S. Hospitals Need to Know to Prepare for Ebola Virus Disease": http://emergency.cdc.gov/coca/transcripts/2014/call-transcript-080514.asp.)

5. Wherever possible, testing should be performed inside the patient's isolation room or inside the isolation facility, using Point-of-Care (POC) instruments and testing methods. **This includes: routine blood chemistry, blood gases, hematology and urinalysis.**

6. Testing that requires transport of samples to laboratories outside the patient's isolation room should be kept to a minimum. Specimens should be double-bagged and placed in a biohazard transportation container. The container should be wiped down with 10% bleach, **hand-carried** to the laboratory (**DO NOT** use a pneumatic tube system) and opened inside a biosafety cabinet.

7. **ALL** specimen manipulations must be performed in a certified Class 2 Biosafety Cabinet (BSC2) in a Biosafety Level 2 (or higher) laboratory, wearing appropriate PPE, including:

   - Impermeable gown with back closure (front button or front snap closing laboratory coats are not acceptable)
   - Double gloves
   - Mask to cover nose and mouth
   - Eye protection such as safety goggles

GUIDANCE FOR SPECIFIC PROCEDURES

Procedure	**Recommendation**
Centrifugation	Procedures requiring centrifugation should be avoided outside the patient isolation room. When performed, it must be with biohazard sealed buckets or rotor.
Chemistry and hematology	See above under "General Points".
Malaria testing	Only thin blood smears should be prepared for Ebola PUIs. These should be prepared inside a BSC2 and should not be removed from the cabinet until they have been fixed and dried. Do not perform thick smears for malaria testing.
Blood Cultures	Specimens should be double-bagged and placed into a biohazard transportation container for transport to the microbiology laboratory. Plastic blood culture bottles may be placed into a continuous monitoring system for diagnosis. Blood culture in glass bottles should be avoided.
Other specimens for bacterial culture	Do not perform "pan-cultures". If essential for patient management, perform all procedures inside a BSC2 with PPE, use shrink seal or parafilm to seal culture plates or tubes. Subsequent colonies can be placed in identification systems.
Wet preps	Should not be performed.
Viral cultures	**DO NOT perform viral culture**, including any rapid culture systems, under any circumstances on any specimen.
Viral or bacterial antigen tests	Rapid antigen tests should be performed inside patient isolation room.
Molecular testing for infectious agents	Ideally, these should be performed with a POC device inside the patient isolation room or isolation facility. Where this is not possible and testing is imperative for patient care, specimens should be transported to the laboratory as above, and initial lysis performed in a BSC2 with PPE, preferably inside a BSL-3 laboratory.
Cross-matching for blood transfusion	This should not be performed. Patient should be treated with volume boosters and, if necessary, O-negative blood transfusion.

Tissue Pathology	Should be kept to a minimum and only performed if essential for patient care. Procedures such as frozen sections and homogenization should not be performed. Tissue preparations such as touch prints and biopsies should be fixed inside the patient isolation room.
Post-mortem examinations	Should not be performed. Consult with CDC as needed.
Specimen storage:	Long-term storage of specimens is discouraged. All specimens collected from Ebola PUIs or positive cases should be isolated from other specimens in the laboratory and disposed of in an appropriate manner as soon as testing is completed (see below).
Packaging and Shipping	If shipment is via commercial transportation, adhere to Category A Substances shipping requirements, unless otherwise specified. (There may be some occasions when Category B, is appropriate depending on available clinical data, and if Ebola virus infection is not the likely cause of disease. Submitters should consult with the nearest IDPH laboratory prior to the shipment of specimens.)
Specimen decontamination and disposal	Autoclave specimens from all PUI if facilities are available. Alternatively, inactivate specimens in 10% bleach for 24 hours, then place in standard biohazard infectious waste disposal. **NOTE: Ebola is a Tier 1 Select Agent (SA). If a patient tests positive for Ebola, any blood or body fluid specimens from a positive patient must be handled and disposed of in accordance with the Select Agent Regulation. Destruction on site must be documented, or specimens transferred to a Tier 1 SA Registered Lab for destruction.**

References:

Document based on guidance from the New York State Department of Health.

Hersberger et al. 2004. Clinical Chemistry. 50: 944-946.

Rollin et al. 2011. Arenaviruses and Filoviruses. In: Manual of Clinical Microbiology. (10th ed). ASM Press.